

LIPID PROFILE

(REF 10-989)

TC+HDL

Test Cassette

(REF 10-987)

(REF 10-986)

TC

Total Cholesterol, HDL Cholesterol and

Triglycerides Panel Test Cassette

Total Cholesterol and HDL Panel

Total Cholesterol Test Cassette

LIPID PROFILE•GLU

Total Cholesterol, HDL Cholesterol, Triglycerides and Glucose Panel Test Cassette (REF 10-991)

TC+HDL+GLU

Total Cholesterol, HDL Cholesterol and Glucose Panel Test Cassette (REF 10-990)

TC.GLU

Total Cholesterol and Glucose Panel Test Cassette (REF 10-988)

CLIA WAIVED - This test is waived under CLIA'88 regulations. Each laboratory or testing site using this test system must have a CLIA Certificate of Waiver. To obtain a Certificate of Waiver, refer to CMS website (http://www.cms.hhs.gov/CLIA/). Laboratories must follow the manufacturer's instructions. If a laboratory modifies the test system instructions, then the test is considered high complexity and subject to all CLIA requirements.

### INTENDED USE / INDICATIONS FOR USE

The Cholestech LDX" System is a small, portable analyzer and test cassette system. The System is for *in vitro* diagnostic use only. The Lipid Profile-CLU Cassette is for the quantitative determination of total cholesterol, HDL (high-density lipoprotein) cholesterol, triglycerides and glucose in whole blood. A TC/HDL (total cholesterol/HDL cholesterol) ratio and estimated values for LDL (low-density lipoprotein) and non-HDL cholesterol are calculated by the Cholestech LDX Analyzer.

- Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.
- HDL (lipoprotein) measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.
- Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.
- Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia\*, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

\*Performance of the Cholestech LDX System has not been tested on samples from newborns.

### SUMMARY and EXPLANATION

Cholesterol is a major cause of atherosclerotic cardiovascular disease (ASCVD) and large clinical trials show that lipid-lowering therapy substantially reduces risk for ASCVD.¹ Recent clinical practice guidelines for cholesterol management from the American College of Cardiology and the American Heart Association recommend a fasting lipid profile consisting of total cholesterol (TC), HDL cholesterol (HDL), LDL cholesterol (LDL), and triglycerides (TRG). In nonfasting individuals, non-HDL levels can identify patients for further evaluation. The National Cholesterol Education Program recommends that for routine patient evaluation and follow-up, LDL should be estimated from measurement of TC, HDL, and TRG using the Friedewald formula.² LDL is used to identify certain patient populations as candidates for lipid-lowering therapy. TC and HDL are employed in algorithms to identify ASCVD risk.² LDL and TRG are used to identify secondary causes of hyperlipidemia, and TRG facilitates selection of certain lipid-lowering agents. Follow-up measurement of these lipid parameters is necessary to ensure that individuals achieve appropriate therapeutic response and are adherent to treatment recommendations.¹

Glucose is the major energy source for the human body and is necessary for the growth, development and maintenance of virtually all cells in the tissues and organs. \*Blood glucose levels are maintained within a relatively narrow range by a combination of interacting factors that decrease the glucose level when it gets too high and increase it when it drops too low. Because this delicate homeostatic mechanism is able to keep glucose levels within such a narrow range, values outside this range generally indicate a disease state. Insulin is the principal hormone regulating glucose levels, and any defect in the production or action of insulin can lead to one of the several forms of diabetes mellitus. Persons with diabetes mellitus may develop a number of serious complications, and some studies have shown that careful control of blood glucose levels may reduce the incidence or delay the onset of these complications.

Total cholesterol, HDL cholesterol, triglycerides and glucose can be measured simultaneously from a single drop of blood using the Cholestech LDX System's rapid, accurate technology. Estimated LDL cholesterol and non-HDL cholesterol and a TC/HDL ratio are calculated using the measured values with software version V3.0 and higher.

# TEST PRINCIPLE

The Cholestech LDX System combines enzymatic methodology<sup>5</sup> and solid-phase technology to measure total cholesterol, HDL cholesterol, triglycerides and glucose. Samples used for testing can be whole blood from a fingerstick (collected in a lithium heparin-coated capillary tube) or venipuncture. The sample is applied to an Cholestech LDX cassette.

The cassette is then placed into the Cholestech LDX Analyzer where a unique system on the cassette separates the plasma from the blood cells. A portion of the plasma flows to the right side of the cassette and is transferred to both the total cholesterol and triglyceride reaction pads. Simultaneously, plasma flows to the left side of the cassette where the low- and very low-density lipoproteins (LDL and VLDL) are precipitated with dextran sulfate (50,000 MW) and magnesium acetate precipitating reagent. The filtrate, containing both glucose and HDL cholesterol, is transferred to both the glucose and HDL cholesterol reaction pads. The Cholestech LDX Analyzer measures total cholesterol and HDL cholesterol by an enzymatic method based on the method formulation of Allain et al,7 and Roeschlau.8 Cholesterol esterase hydrolyzes the cholesterol esters in the filtrate or plasma to free cholesterol and the corresponding fatty acid. Cholesterol oxidase, in the presence of oxygen, oxidizes free cholesterol to cholest-4-ene-3-one and hydrogen peroxide. In a reaction catalyzed by horseradish peroxidase, the peroxide reacts with 4-aminoantipyrine and N-ethyl-N-sulfohydroxypropyl-m-toluidine, sodium salt (TOOS) to form a purplecolored quinoneimine dye proportional to the total cholesterol and HDL cholesterol concentrations of the sample.



The Cholestech LDX Analyzer measures triglycerides by an enzymatic method based on the hydrolysis of triglycerides by lipase to glycerol and free fatty acids. Glycerol, in a reaction catalyzed by glycerol kinase, is converted to glycerol-3-phosphate. In a third reaction, glycerol-3-phosphate is oxidized by glycerol phosphate oxidase to dihydroxyacetone phosphate and hydrogen peroxide. The color reaction utilizing horseradish peroxidase is the same as for the total cholesterol and HDL cholesterol.

Triglycerides + H <sub>2</sub> O	Lipase	Glycerol + Free fatty acids
Glycerol + ATP	Glycerol kinase + Mg <sup>2+</sup>	Glycerol-3-phosphate + ADP
${\sf Glycerol\text{-}3\text{-}phosphate} + {\sf O_2}$	Glycerol phosphate Oxidase	Dihydroxyacetone phosphate + $H_2O_2$
2 H <sub>2</sub> O <sub>2</sub> + 4-Aminoantipyrine + TOOS	Peroxidase	Quinoneimine dye + 4 H <sub>2</sub> O

The Cholestech LDX Analyzer measures glucose by an enzymatic method that uses glucose oxidase to catalyze the oxidation of glucose to gluconolactone and hydrogen peroxide. The color reaction utilizing horseradish peroxidase is the same as that for total cholesterol, HDL cholesterol and triglycerides. The resultant color in all the reactions is measured by reflectance photometry.

A brown (magnetic) stripe on each cassette contains the calibration information required for the Cholestech LDX Analyzer to convert the reflectance reading (% R) to the total cholesterol, HDL cholesterol, triglycerides and glucose concentrations.

### REAGENTS

### Materials Provided

Cholestech LDX Lipid Profile+GLU, Lipid Profile, TC+HDL-GLU, TC+HDL, TC+GLU, or TC Cassettes

Each cassette contains a minimum of:

	IC	HDL	IRG	GL
Dextran sulfate (50,000 M.W.), µg	-	17.2	-	-
Magnesium acetate, µg	_	153	-	-
Cholesterol esterase, U (Pseudomonas species)	0.287	0.287	-	-
Lipase, U	-	-	53.9	-
(Bacterial source)				

	TC	HDL	TRG	GLU
Cholesterol oxidase, U (Pseudomonas species)	0.049	0.049	-	-
Peroxidase (horseradish), U	0.266	0.266	0.133	0.133
4-Aminoantipyrine, μg	5.39	2.52	2.73	5.11
N-Ethyl-N-sulfohydroxypropyl m-toluidine, sodium salt, µg	77.0	16.2	16.1	32.3
Glycerol kinase, U (Cellulomonas species)	-	-	0.399	-
Glucose oxidase, U	-	-	-	0.539
(Cellulomonas species) Adenosine triphosphate, µg (Bacterial source)	-	-	18.8	-
Glycerol phosphate oxidase, U (Aerococcus viridans)	-	-	0.238	-
Magnesium chloride, µg	-	-	1.37	-
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Nonreactive ingredients: buffers and stabilizers

### Materials Required But Not Provided

- Cholestech LDX System
- · Alcohol swabs and gauze for cleaning puncture site
- Lancets for capillary blood collection
- Cholestech LDX 40 µL Lithium Heparin Capillary Tubes
- Cholestech LDX Capillary Plungers
- Gloves
- Biohazard waste containers
- · Quality control material
- MiniPet® Pipette and tips or micropipetter that will deliver 40 μL for use with venipuncture samples and quality control material
- Vacuum collection tubes, needles, tube holders and sample tubes if the sample is to be collected by venipuncture

### WARNINGS and PRECAUTIONS

For professional in vitro diagnostic use only.

All blood samples, containers, capillary tubes and materials that have come in contact with blood should be handled as if capable of transmitting infectious disease and discarded into a biohazardous waste container after use.

# STORAGE and HANDLING

### Cassette Storage and Stability

Cassettes must be stored in the sealed foil pouches.

Place cassettes in the refrigerator after receipt. Cassettes may be used until the date printed on the pouch when stored in a refrigerator ( $36-46^{\circ}F/2-8^{\circ}C$ ).

The cassettes may be stored for up to 30 days at room temperature (48–86°F / 9–30°C). The new expiration date is the date the cassettes are placed at room temperature plus 30 days. Write the new expiration date on the side of the cassette box in the space provided.

**Note:** Once the cassettes have been stored at room temperature, they should not be returned to the refrigerator.

- . Do not use a cassette beyond the printed expiration date.
- Do not use a cassette that has been stored at room temperature for more than 30 days.
- Do not reuse cassettes.

# Cassette Handling

Cassettes should sit at room temperature for 10 minutes before opening the pouch.

Use the cassette as soon as the pouch is opened.

### SPECIMEN COLLECTION and HANDLING

### Sample Type

The Cholestech LDX System is CLIA waived for fingerstick or venous whole blood unprocessed samples only.

### Sample Requirement

Sample Volume: 40 μL of whole blood.

### Fingerstick whole blood

- When testing triglycerides the subject should fast for 9-12 hours before the sample is collected. Subjects should fast for at least 8 hours for glucose tests before the sample is collected.
- $\bullet$  Collect the sample from a fingerstick into a Cholestech LDX 40  $\mu L$  Capillary Tube. (See the Fingerstick Procedure below).
- · Place the blood into the cassette within 8 minutes after collection.
- Blood from the fingerstick should flow freely. Too much squeezing of the finger may cause inaccurate results.

### Venous whole blood

Collect blood into a green-top tube (heparin anticoagulant).

Note: Do not use a tube with any other additives because it may cause inaccurate results.

- Use a pipette and tip to place blood into the cassette.
- Whole blood should be used within 30 minutes.
- Samples should be at room temperature for testing.
- . Mix all samples by gently inverting at least 7 times before testing.
- Glucose levels decrease 5 to 10 mg/dL (0.28 to 0.55 mmol/L) per hour in whole blood at room temperature.

## TEST PROCEDURE

### Calibration

No calibration is performed by the user. Test information is encoded on the brown stripe of the cassette. The brown magnetic stripe is read by the Cholestech LDX Analyzer each time a cassette is run.

An Optics Check should be run on the analyzer each day that patient samples are tested. See the Cholestech LDX User Manual for instructions.

**Note:** A warm hand and good blood flow from the puncture site are essential in order to collect a good capillary sample.

WARNING: Squeezing the finger excessively may cause inaccurate test results.

### Fingerstick Procedure

- 1. The patient should sit quietly for five minutes before the blood sample is collected. 2. Put a capillary plunger into the end of a Cholestech LDX 40  $\mu$ L Capillary Tube with
- the red mark. Set aside.

  3. Choose a spot that is on the side of one of the center fingers of either hand. The
- Choose a spot that is on the side of one of the center fingers of either hand. In fingers and hands should be warm to the touch. To warm the hand, you can:
   a. Wash the patient's hand with warm water, or...
  - b. Apply a warm (not hot) compress to the hand for several minutes, or...
  - Gently massage the finger from the base to the tip several times to bring the blood to the fingertip.
- Clean the site with an alcohol swab. Dry thoroughly with a gauze pad before pricking the finger.
- Firmly prick the selected site with a lancet.
- Squeeze the finger gently to obtain a large drop of blood. Wipe away this first drop
  of blood as it may contain tissue fluid.
- Squeeze the finger gently again while holding it downward until a second large drop
  of blood forms. Do not milk the finger. The puncture should provide a free-flowing
  drop of blood.
- 8. Hold the capillary tube horizontally or at a slightly descending angle by the end with the plunger. Touch it to the drop of blood without touching the skin. The tube will fill by capillary action to the black mark. Do not collect air bubbles. If it is necessary to collect another drop of blood, wipe the finger with gauze then massage again from base to tip until a large drop of blood forms.
- 9. Fill the capillary tube within 10 seconds.
- Wipe off any excess blood from the finger and have the patient apply pressure to the puncture until the bleeding stops.

### Using the Minipet® Pipette

Use this procedure to apply a venous blood sample, or control, calibration verification or proficiency testing materials to the cassette. Any pipette that can deliver 40 µL may be used.

- Firmly attach the pipette tip to the end of the 40 μL MiniPet® Pipette. Use a new tip for each sample.
- To fill the pipette, push the plunger down as far as you can. Place the pipette tip midway into the sample and slowly release the plunger. Confirm that no air bubbles are in the pipette tip.
- Place the pipette tip into the cassette sample well. Dispense the sample into the cassette sample well by pressing the plunger down. Move the pipette tip out of the sample well before releasing the plunger again.
- 4. Remove the pipette tip and throw it away in a biohazard waste container.

  Note: If the plunger is released before the pipette tip is out of the sample well, it will remove

Note: Keep the cassette horizontal at all times after applying the sample.

# Running a Test

the sample just dispensed.

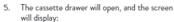
- If the cassettes have been refrigerated, allow them to come to room temperature (at least 10 minutes) before opening.
- Make sure the analyzer is plugged in and has warmed up.
- Remove the cassette from its pouch. Hold the cassette by the short sides only. Do not touch the black bar or the magnetic stripe. Place the cassette on a flat surface.

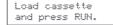
Note: Gloves should be worn whenever working with blood samples.

 Press RUN. The analyzer will do a selftest, and the screen will display:

Selftest running.

Selftest OK





 Place the sample into the cassette well. Use an Cholestech LDX Capillary Tube for fingerstick samples. Use a 40 µL pipette for venous blood samples and quality control, calibration verification, and proficiency testing materials.





Note: Fingerstick samples must be applied within eight (8) minutes or the blood will clot.

- Keep the cassette flat after the sample has been applied. WARNING: Allowing
  the sample to sit in the cassette will cause inaccurate results. Immediately place
  the cassette into the drawer of the analyzer. The black reaction bar must face
  toward the analyzer. The brown magnetic stripe must be on the right.
- DO NOT PUSH IN THE DRAWER. Press RUN. The drawer will close. During the test, the screen will display:

[Test Name(s)] Running\*\*\*

- or proficiency testing material into a biohazardous waste container.
- 10. When the test is complete, the analyzer will beep, and the screen will display:

9. Put everything that touched the blood samples or control, calibration verification,

[Test Name]=### warnings

- 11. Press DATA to view additional results.
- 12. When the results are outside the measuring range of the test, the screen will display:

[Test Name]>###
or
[Test Name]<###

 If there is a problem with the test, a message will appear on the screen. See the Troubleshooting section of the Cholestech LDX System User Manual if this happens.

Please call Abbott Product Support to report any problems or if you have questions about the operation of the Cholestech LDX System.

14. When the drawer opens, remove the cassette, and put it in a biohazardous waste

- container. Leave the analyzer drawer empty when not in use.
- 15. Record the results on the appropriate form.
- 16. To run another cassette, press **RUN**. The screen will display:

Load cassette and press RUN.

17. Repeat step 3, and steps 6 through 15.

**Note:** If you do not want to run another test and the drawer is open, press STOP to close the drawer.

18. Otherwise, after four minutes a beep will sound and the screen will display:

System timeout RUN to continue

19. If necessary, press the DATA button to view the results from the last cassette used.

Note: Pressing the RUN button will erase the previous result.

# RESULTS

Test results will be displayed on the screen when the test is complete. Calculated results are displayed after the DATA button is pressed.

### To convert:

	mg/dL to mmol/L	mmol/L to mg/dL
	divide mg/dL by	multiply mmol/L by
TC	38.664	38.664
HDL	38.664	38.664
ΓRG	88.54	88.54
LDL	38.664	38.664
GLU	18.018	18.018

# QUALITY CONTROL

External quality control material should be run routinely to show that your system is giving accurate results. We recommend the following quality control procedures for the Cholestech LDX System.

Liquid Level 1 and Level 2 controls that work well with the Cholestech LDX System are available. If you use other controls, you will need to establish ranges for the Cholestech

- Follow the instructions that come with your controls.
- · Check the expiration date before use. Do not use if expired.
- · See "Running a Test" for the procedure.

### External Quality Control

External control material should be used to demonstrate that the reagents and the assay procedure perform properly. Good Laboratory Practice principles suggest that controls should be run whenever the laboratory director has any question about test system integrity, reagent storage conditions, or the reliability of any test result.

If the controls do not perform as expected, repeat the test or contact Abbott Product Support before testing patient samples.

Controls should be tested:

- With each new lot of cassettes:
- · With every new shipment of cassettes, even if the lot has been received previously;
- . When reagents may have been stored or handled in a way that can degrade their performance:
- · As otherwise required by your laboratory's standard quality control procedures;
- · As otherwise required by federal, state and local guidelines.

# Record the results in a Quality Control Log.

The quality control results should be in range before testing patient samples. See the Cholestech LDX System User Manual if they are not. Please call Abbott Product Support to report any problems or if you have any questions about quality control.

### LIMITATIONS

Analyte	Measuring Range	For results outside the measuring ran the LDX displays:	
	mg/dL (mmol/L)	Low	High
TC	100 – 500	<100 mg/dL	>500 mg/dL
	(2.59 –12.9)	(<2.59 mmol/L)	(>12.9 mmol/L)
HDL	15 –100	<15 mg/dL	>100 mg/dL
	(0.39 – 2.59)	(<0.39 mmol/L)	(>2.59 mmol/L)
TRG	45 - 650	<45 mg/dL	>650 mg/dL
	(0.51-7.34)	(<0.51 mmol/L)	(>7.34 mmol/L)
GLU 50 – 500		<50 mg/dL	>500 mg/dL
(2.78 – 27.8)		(<2.78 mmol/L)	(>27.8 mmol/L)

### Additional Limitations That Display N/A:

- If the measured value of TRG is >650 mg/dL (>7.34 mmol/L), the Cholestech LDX Analyzer displays "N/A" for HDL.
- If the measured value of TRG is >400 mg/dL (>4.51 mmol/L), the Cholestech LDX Analyzer displays "N/A" for the LDL estimate.
- . If the measured value of TC, HDL or TRG is outside the measuring range, the Cholestech LDX Analyzer displays "N/A" for the LDL estimate.

### Additional Limitations:

- The glucose test is specific for D-glucose. Other sugars that may be present in the blood do not react in the glucose test (i.e., fructose, lactose).
- · Samples with total cholesterol, HDL cholesterol, triglyceride or glucose values outside the measuring range should be sent to a laboratory for testing.
- · Performance of the Cholestech LDX System has not been tested on samples from
- · Blood glucose results performed at altitudes above 5000 feet have not been validated. Some substances may cause inaccurate results with enzymatic tests. The substances listed below were tested for interference with all analytes. Less than 10% interference was seen at the levels shown.

### Substance Concentration (mg/dL)

Ascorbic Acid	1	Hemoglobin	125
Bilirubin	5	Lactose	100
Creatinine	30	Lovastatin (Mevacor)	4
Cysteine	10	Nicotinic Acid (Niacin)	10
Fructose	30	Urea	500
Gemfibrozil (Lopid)	15	Uric Acid	15
Glutathione	1		

- . Hematocrits between 30% and 49% do not affect results.
- Blood collection tubes with glycerol should not be used for the triglyceride test.
- . Hand creams and soaps with glycerol may cause falsely high triglyceride results.
- The triglyceride test measures triglycerides and free glycerol. Free glycerol usually is less than 20 mg/dL.10,11
- There may be a 6–7% difference in the glucose levels of fingerstick and venous blood.<sup>12</sup>

### EXPECTED VALUES

Lipid values are interpreted according to clinical practice guidelines or recommendations that are subject to change over time. Interpretive information for all lipid values is not contained in a single guideline. The following information was compiled from recent guidelines or recommendations of the American College of Cardiology, American Heart Association, and National Lipid Association. 3,13,14

## TC, HDL, TRG, LDL and Non-HDL

Analyte	mg/dL	mmol/L	Classification
TC <sup>3,13</sup>	170	4.40	Optimal
HDL	50	1.29	Optimal 3,13
	<40 (men)	<1.03	Low <sup>14</sup>
	<50 (women)	<1.29	Low <sup>14</sup>
TRG <sup>14</sup>	<150	<1.69	Normal
	150 - 199	1.69 - 2.25	Borderline high
	200 - 499	2.26 - 5.64	High
	≥500	≥5.65	Very high
LDL <sup>14</sup>	<100	<2.59	Desirable
	100 - 129	2.59 - 3.34	Above desirable
	130 – 159	3.36 - 4.11	Borderline high
	160 – 189	4.14 - 4.89	High
	≥190	≥4.91	Very high
N. HBIY	400	201	D : 11
Non-HDL <sup>14</sup>	<130	<3.36	Desirable
	130 – 159	3.36 – 4.11	Above desirable
	160 – 189	4.14 - 4.89	Borderline high
	190 - 219	4.91 - 5.66	High
	≥220	≥5.69	Very high

### TC/HDL Ratio

Clinical practice guidelines do not comment on use of the ratio of total to HDL cholesterol. Various authors have suggested that the TC/HDL ratio is the strongest lipid risk factor and can be a useful summary of coronary heart disease risk. 15,16 A ratio of 4.5 or less is desirable. A ratio greater than 6.0 suggests a high risk of coronary heart disease. 15

The American Diabetes Association has identified categories of increased risk for diabetes based upon glucose:1

- Fasting plasma glucose (FPG) 100-125 mg/dL (5.6-6.9 mmol/L); impaired fasting glucose
- 2-hr plasma glucose in the 75-g oral glucose tolerance test (OGTT) 140-199 mg/dL (7.8-11.0 mmol/L); impaired glucose tolerance

For these tests, risk is continuous, extending below the lower limit of the range and becoming disproportionately greater at higher ends of the range.

The American Diabetes Association has criteria for the diagnosis of diabetes mellitus based upon glucose:

- . FPG ≥126 mg/dL (7.0 mmol/l). Fasting is defined as no caloric intake for at least 8 hr.
- 2-h plasma glucose ≥200 mg/dL (11.1 mmol/L) during an OGTT. The test should be performed as described by the World Health Organization, using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water.
- . In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose ≥200 mg/dL (11.1 mmol/L).

In the absence of unequivocal hyperglycemia, diagnosis should be confirmed by repeat testing. When screening for diabetes, any abnormal glucose result should be referred to a physician for further follow-up.

# PERFORMANCE CHARACTERISTICS

Representative Data: results in individual laboratories may vary from these data. Individual laboratories results may vary from this study due to differences in the testing protocol, and between instruments, calibrations, reagents, and replicates.

Within-Run Precision

Day-to-Day Precision

Precision		un Precision od (heparin)	Commercial Control  Material		
	Level 1	Level 2	Level 1	Level 2	
Total Cholesterol, n =	10	10	20	20	
X (mg/dL) =	299	184	161	244	
SD (mg/dL) =	7.3	4.6	4.3	8.6	
CV (%) =	2.4	2.5	2.6	3.5	
HDL Cholesterol, n =	10	10	20	20	
X (mg/dL) =	29	46	29	46	
SD (mg/dL) =	1.0	2.2	1.3	2.9	
CV (%) =	3.3	4.9	4.4	6.4	
Triglycerides, n =	10	10	20	20	
X (mg/dL) =	362	256	121	276	
SD (mg/dL) =	13.1	4.0	2.8	8.7	
CV (%) =	3.6	1.6	2.3	3.2	
LDL Cholesterol, n =	10	10	20	20	
X (mg/dL) =	197	87	108	143	
SD (mg/dL) =	7.5	4.3	4.6	8.4	
CV (%) =	3.8	4.9	4.3	5.9	
Glucose, n =	10	10	20	20	
X (mg/dL) =	103	127	103	311	
SD (mg/dL) =	6.4	5.7	3.6	15.4	
CV (%) =	6.2	4.5	3.5	4.9	

# ACCURACY (METHOD COMPARISON)

The cassette total cholesterol was compared with a validated method traceable to the CDCmodified Abell-Kendall reference method traceable to National Institute of Standards and Technology (NIST) standards.

The cassette HDL cholesterol was compared with a validated method, utilizing dextran sulfate/magnesium chloride precipitation and enzymatic cholesterol determination. The HDL cholesterol comparison method is based on the selected method for HDL cholesterol<sup>5</sup> and has documented agreement with the CDC Reference Method.

The cassette triglyceride test was compared with a validated method, utilizing hydrolysis with lipase. The comparison method has documented agreement with a CDC Reference Method. The cassette estimated LDL was compared to that calculated from the above validated total cholesterol, HDL cholesterol and triglycerides methods.

The range of values tested (mg/dL) were as follows: 120 - 300

26 - 85 40 - 500 GLU 25 - 575

### Results

X = Reference Method (serum)

Y = Cholestech LDX Analyzer (venous whole blood) . . .

Analyte	No. of Pairs	Slope	y-intercept	Correlation Coefficient	Bias at
Total cholesterol	40	0.98	2.41	0.97	200 -19
HDL cholesterol	40	0.97	0.23	0.95	35 -29
Triglycerides	40	1.0	0.13	0.99	250 0
Glucose	40	0.99	1.01	0.98	150 09

### LIMITED WARRANTY

For the applicable warranty period, Abbott warrants that each product shall be (I) of good quality and free of material defects, (II) function in accordance with the material specifications referenced in the product manual, and (III) approved by the proper governmental agencies required for the sale of products for their intended use (the "Limited Warranty"). If the product fails to meet the requirement of the limited warranty, then as a customer's sole remedy, Abbott shall either repair or replace, at Abbott's discretion, the product. Except for the limited warranty stated in this section, Abbott disclaims any and all warranties, express or implied, including but not limited to, any warranty of merchantability, fitness for a particular purpose and non-infringement regarding the product. Abbott's maximum liability with any customer claim shall not exceed the net product price paid by customer. Neither party shall be liable to the other party for special, incidental or consequential damages, including, without limitation, loss of business, profits, data or revenue, even if a party receives notice in advance that these kinds of damages might result.

The Limited Warranty above shall not apply if the customer has subjected the product to physical abuse, misuse, abnormal use, use inconsistent with the product Manual or Insert, fraud, tampering, unusual physical stress, negligence or accidents. Any warranty claim by customer pursuant to the Limited Warranty shall be made in writing within the applicable Limited Warranty period.

# RETURN POLICY

Please contact Abbott Product Support prior to returning any defective components. Refer to Contact Abbott section for additional information.

# CONTACT ABBOTT

# Abbott Product Support

Contact one of the following Abbott Product Support Care Centers or your local distributor if you have any questions regarding the use of your Abbott product. You may

also contact us at www	w.globalpointorcare.abbott.	
Region	Phone	E Mail Address
Europe & Middle East	+ (44) 161 483 9032	${\sf EMEproduct support} @abbott.com$
Asia Pacific	+ (61) 7 3363 7711	APproductsupport@abbott.com
Africa, Russia, & CIS	+ (44) 161 483 9032	${\sf ARCISproduct support@abbott.com}$
Latin America	+ (57) 4824033 (ext. 2)	LAproductsupport@abbott.com
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### Abbott Customer Service

Contact the following Abbott Service Care Center or your local distributor for order and billing assistance. You may also contact us at www.globalpointofcare.abbott.

E Mail Address + (1) 877 441 7440 clientservices@abbott.com

**EN** For a copy of this product's instructions for use in English please visit our website.

CS Kopii návodu k použití tohoto výrobku v češtině najdete na našich webových stránkách.

DA Du kan finde en kopi af denne brugerhåndbog på dansk på vores websted.

DE Eine Kopie der Gebrauchsanweisung für dieses Produkt in deutscher Sprache finden Sie auf ΕΙ Για ένα αντίγραφο των οδηγιών χρήσης αυτού του προϊόντος στα Ελληνικά,

παρακαλούμε επισκεφθείτε τον ιστότοπό μας.

ES Para obtener una copia de las instrucciones de uso de este producto en español, visite

ET Toote eestikeelse kasutusjuhendi saamiseks külastage meie veebisaiti.

FR Pour obtenir un exemplaire du mode d'emploi de ce produit en français, veuillez consulter notre site Internet.

HU A termékutasítások magyar nyelvű megtekintéséhez keresse fel weboldalunkat.

ID Untuk salinan petunjuk penggunaan produk ini dalam bahasa Inggris, kunjungi situs web kami. IT Per una copia delle istruzioni di questo prodotto per l'uso in italiano, si prega di visitare il nostro sito web.

KO 본 제품의 한국어 사용 지침을 보시려면 웹사이트를 방문하십시오.

NL Voor een kopie van de gebruiksinstructies van dit product in het Nederlands verwijzen wij u

NO For et eksemplar av dette produktets brukerveiledning på norsk kan du gå til vår nettside. PL Kopia instrukcji użycia tego produktu w języku polskim jest zamieszczona na naszej witrynie internetowei PT Para obter uma cópia das instruções de utilização deste produto em português, viste o nosso

PT-BR Para uma cópia das instruções de uso deste produto em português, visite nosso website.

RO Pentru o copie a Instrucțiunilor de utilizare pentru acest produs in limba romană vizitați

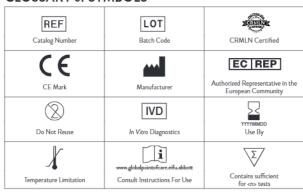
SK Kópiu návodu na používanie tohto produktu v slovenčine nájdete na našej webovej stránke. SV Besök vår webbplats för att få en kopia av bruksanvisningen på svenska för denna produkt. TH หากต้องการสำาเนาค่มีอเลิตภัณฑ์นี้เป็นภาษาไทย โปรตไปที่เว็บไซต์ของเรา

TR Bu ürüne ilişkin kullanım talimatlarının Türkçe dilindeki bir kopyası için web sitemizi ziyaret

# REFERENCES

- 1. Stone NJ, Robinson JG, Lichtenstein AH, et al. 2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation 2014; 129:S1-S45.
- Bachorik PS, Ross JW, for the National Cholesterol Education Program Working Group on Lipoprotein Measurement. National Cholesterol Education Program recommendation: for measurement of low-density lipoprotein cholesterol: executive summary. Clin Chem 1995-41-1414-20
- 3. Goff DC, Lloyd-Jones DM, Bennett G, et al. 2013 ACC/AHA guideline on the assessment of cardiovascular risk: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation 2014; 129:S49-S73.
- 4. Tietz NW, ed. Fundamentals of Clinical Chemistry. Philadelphia, Pa.: WB Saunders Co., 1987. 5. Siedel J, Hagele EO, Ziegenhorn J, et al. Reagent for the enzymatic determination of serum total
- cholesterol with improved lipolytic efficiency. Clin Chem 1983;29:1075-80. 6. Warnick GR, Benderson J, Albers JJ. Dextran sulfate-Mg2+ precipitation procedure for
- quantitation of high density-lipoprotein cholesterol. Selected Methods for Clinical Chemistry 1983:10:91-9.
- 7. Allain CC, Poon LS, Chan CS, et al. Enzymatic determination of total serum cholesterol. Clin Chem 1974:20:470-5 8. Roeschlau P, Bernt E, Gruber W. Enzymatische bestimmung des gesamtcholesterins im serum. Z
- Klin Chem Klin Biochem 1974;12:226. 9. Fossati P, Prencipe L. Serum triglycerides determined colorimetrically with an enzyme that
- produces hydrogen peroxide. Clin Chem 1982;28:2077-80. Jessen RH, Dass CJ, Eckfeldt JH. Do enzymatic analyses of serum triglycerides really need blanking for free glycerol? Clin Chem 1990;36:1372-5.
- 11. Tietz NW, ed. Clinical Guide to Laboratory Tests. 2nd ed. Philadelphia, Pa.: WB Saunders Co., 1990.
- 12. Blumenfeld TA, Hertelendy WG, Ford SH. Simultaneously obtained skin- puncture serum, skinpuncture plasma, and venous serum compared, and effects of warming the skin before puncture. Clin Chem 1977;23:1705-10.
- CV Risk Calculator. http://professional.heart.org/professional/GuidelinesStatements/ PreventionGuidelines/UCM\_457698\_Prevention-Guidelines.jsp, accessed 5/26/17.
- 14. Jacobson TA, Ito MK, Maki KC, et al. National Lipid Association recommendations for patientcentered management of dyslipidemia: Part 1 - executive summary. J Clin Lipidol 2014;8:473-88.
- 15. Castelli WP, Abbott RD, McNamara PM. Summary estimates of cholesterol used to predict coronary heart disease. Circulation 1983;67:730-4.
- 16. Kinosian B, Glick H, Garland G. Cholesterol and coronary heart disease: predicting risks by levels and ratios. Ann Intern Med 1994;121:641-7.
- 17. American Diabetes Association. Standards of medical care in diabetes—2017, 2. classification and diagnosis of diabetes. Diabetes Care 2017;40(Suppl.1):S11-24.

# GLOSSARY of SYMBOLS





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